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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/827,255	04/05/2001	Jeffrey Tze Fei Wong	1441830001336	4343

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BAKER & MCKENZIE
14TH FLOOR, HUTCHISON HOUSE
10 HARCOURT ROAD, CENTRAL
HONG KONG,
HONG KONG

EXAMINER

SCHMIDT, MARY M

ART UNIT	PAPER NUMBER
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1635

DATE MAILED: 02/06/2003

13

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/827,255

Applicant(s)

WONG ET AL.

Examiner

Mary M. Schmidt

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 05 December 2002.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-7,9 and 10 is/are pending in the application.
- 4a) Of the above claim(s) 10 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-7 and 9 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 05 April 2001 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____.
- 4) ☐ Interview Summary (PTO-413) Paper No(s). _____.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____.

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DETAILED ACTION

1. Newly submitted claim 10 is directed to an invention that is independent or distinct from the invention originally claimed for the following reasons: Claim 10 is drawn to a method of preparing a therapeutic agent to a tissue expressing asialoglycoprotein receptors comprising delivery to the tissue an effective amount of the agent encapsulated in a liposome having a molar PC:Chol:PS ratio 11:4:0.025 coupled to desialyated glycoprotein alpha 1 by an avidin-biotin or thiol-maleamide linkages. Claim 10 is thus a method of making the claimed composition suitable for the claimed methods of administration. Since the original invention is drawn to compositions and methods of delivery of the therapeutic agent, claims 1-7 and 9, the new claim 10 drawn to methods of making is restrictable under MPEP 806.05(I).

2. Since applicant has received an action on the merits for the originally presented invention, this invention has been constructively elected by original presentation for prosecution on the merits. Accordingly, claim 10 is withdrawn from consideration as being directed to a non-elected invention. See 37 CFR 1.142(b) and MPEP § 821.03.

Claim Rejections - 35 USC § 112

3. The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

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4. Claims 1-7 and 9 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for liposome compositions having PC:Chol:PS ratio of 11:4:0.025 encompassing doxorubicin as the therapeutic agent coupled to alpha1 acid-glycoprotein by avidin-biotin bridges does not reasonably provide enablement for any liposome composition for the targeted delivery of a therapeutic agent to a tissue expressing asialoglycoprotein receptors as claimed. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention commensurate in scope with these claims for the same reasons of record as set forth in the Official action mailed 08/06/02.

Applicant's arguments filed 12/05/02 have been fully considered but they are not persuasive.

Applicants' response addresses the previous rejection which limited applicant to the breath of treatment with the liposome compositions having PC:Chol:PS ratio of 11:4:0.025 encompassing doxorubicin as the therapeutic agent coupled to alpha1 acid-glycoprotein, to cells in cell culture and mice. Please note the instant rejection has been modified to remove this limitation, and the claims are not considered enabled for treatment of cancer in whole organisms based on the mice data provided in the instant specification as filed (pages 11-13).

Applicant further states on page 4 of the response that "Applicants believe structurally similar compounds, which have been proven, in vivo, have been effective as chemotherapeutic agents against various tumor models. As supported, *In re Brana*, supra, Applicants should not

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have been required to substantiate their presumptively correct disclosure to avoid a rejection under the first paragraph of 112.”

However, the question of enablement under 35 U.S.C. 112, first paragraph, includes the determination of the level of unpredictability in the art prior to the time of the instant application as filed. As pointed out by application in the previous response filed 5/17/02, pages 3-6, and in the Schwonzen et al. quote “[t]he combination of paclitaxel and doxorubicin or epirubicin is highly active against metastatic breast cancer, yet may produce congestive heart failure.” Thus, the art teaches that use of different therapeutic compositions is *unpredictable*, and the rejection under 35 U.S.C. 112, is proper.

5. The closest prior art was taught in Official Action on the merits mailed . 11/06/01 as Allen et al., Perez-Solar et al., Pratt et al., Martin, Hortobagyi, Menezes et al., Neitchev et al. and Mayer et al.

6. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after

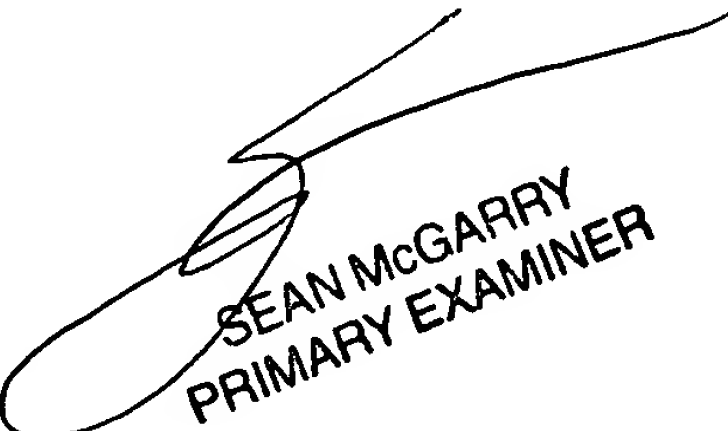
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the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

7. Any inquiry concerning this communication or earlier communications from the examiner should be directed to *Mary M. Schmidt*, whose telephone number is (703) 308-4471.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, *John LeGuyader*, may be reached at (703) 308-0447.

Any inquiry of a general nature or relating to the status of this application should be directed to *Katrina Turner*, whose telephone number is (703) 305-3413.



SEAN MCGARRY
PRIMARY EXAMINER

M. M. Schmidt
February 4, 2003

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